



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1005 5 MAY 13 P1:35

Joanne Robinett
Director, Regulatory Affairs
Innovative Science Solutions, LLC
67 Park Place East
Morristown, NJ 07960

Re: Docket No. 77N-0094

Dear Ms. Robinett:

This is in reference to the data sent in support of citizen petition (CP-16) dated February 11, 2003, filed under Docket No. 77N-0094 in the Dockets Management Branch. The petition requests that the Agency approve expanded cardiovascular indications and professional labeling for the use of an aspirin regimen (75mg – 325mg) in reducing the risk of a first myocardial infarction in at-risk patients. This Citizen Petition also seeks to include the primary prevention indication for ischemic stroke, acute MI, transient ischemic attack, unstable angina pectoris, prevention of recurrent MI, and chronic stable angina pectoris in the professional labeling.

We thank you for your efforts in obtaining the datasets for the Primary Prevention Project, Thrombosis Prevention Trial and US Physicians trial for Agency consideration. The Division of Cardio-Renal Drug Products has had a preliminary look at the TPT datasets submitted to dockets by Dr. Colin Baigent; however, they do **not** include silent MIs, which was the major rationale behind obtaining these data for review. The Division expects that within **30 days** it will submit final comments to the Division of Over-the-Counter Drug Products which will then respond to the Citizen Petition.

If you have any questions regarding this matter, please call Ms. Meg Pease-Fye at (301) 594-5327 or Dr. Walter Ellenberg at (301) 827-2279. Please refer to the docket and comment numbers noted above, and submit all inquiries to the The Division of Dockets Management (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely,

Norman Stockbridge, M.D., Ph.D.,
Acting Director,
Division for Cardio-Renal Drug Products
Office of Drug Evaluation I

77N-0094

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M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 5/11/05

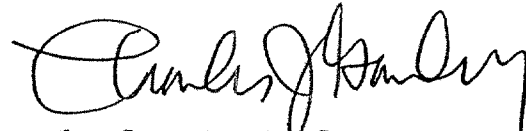
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 77N-0094

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment